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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,581	09/29/2003	Peter Bockstegers	07883.0063	1494

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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,581	Applicant(s) BOEKSTEGERS ET AL	
	Examiner Thomas J. Sweet	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.

4a) Of the above claim(s) 7, 8, 11-13, 15-16, 18, 19, 23-29, 32, 41-42, 45-106 and 109-112 is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 14, 17, 20-22, 30, 31, 33-40, 43, 44, 107 and 108 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/11/05 & 9/6/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Claims 7, 8, 11-13, 15-16, 18, 19, 23-29, 32, 41-42, 45-106 and 109-112 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/27/2006. Claims 7, 8, 11-13, 15-16, 19 and 41-42 have been withdrawn in addition to the claims listed by the applicant, since the disclosure of figs. 10A and 10D is merely restricted which does not support obstructing the coronary vein during any part of the cardiac cycle.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-10, 14, 17, 20-22, 30-31, 33, 35-40, 43-44 and 107-108 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: forming a passage, since the disclosure does not state that the passage is naturally occurring and by disclosure the passage is necessary for retrograde flow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-10, 14, 17, 20-22, 30-31, 36, 38-40 and 107-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalev et al (WO 01/72239). Shalev et al discloses a method of treating a heart (pages 8-9); measuring an internal pressure of a coronary vein (determining the hemodynamic effect, which inherently includes obtaining internal pressure of the coronary vein since increasing pressure in the coronary sinus is a desired effect) so as to determine a measured internal pressure, flowing blood through a passageway (the coronary artery) between a blood-containing anatomical structure (the heart via the aorta) and the coronary vein so as to allow retrograde blood flow in the coronary vein (blood is supplied which could flow retrograde); and based on the measured internal pressure (selecting a reducer having suitable geometry to achieve said hemodynamic effect), at least partially obstructing the coronary vein (via the reducer) at a location upstream of the passageway relative to a direction of the retrograde blood flow (the coronary sinus is upstream from the retrograde flow and the coronary artery is farther upstream in that direction via the circulatory system).

With regard to claims 2 and 3, selecting an amount of obstruction based on the measured internal pressure performed before the flowing of the blood through the passageway (part of the

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hemodynamic effect determination, inherently requires a base level determination and the results to compare).

With regard to claim 4, selecting the location upstream of the passageway based on the measured internal pressure (i.e. suitable geometry).

With regard to claims 5-6, 14, 17, 39-40, at least some antegrade blood flow past the location during at least a portion of and through out a cardiac cycle (i.e. the implant include a flow path)

With regard to claims 9 and 10, selecting the implant from a plurality of implants based on the measured internal pressure (selecting a reducer having suitable geometry).

With regard to claims 20-22, the implant is basically a restricted stent (expandable by a balloon and deformable).

With regard to claims 30-31 and 38, left ventricle connects to the coronary artery via a passage through the circulatory system.

With regard to claim 107, maintaining the internal pressure approximately within a predetermined pressure range is inherent since the circulatory system maintains a pressure range between systolic and diastolic, so the pressure range can only fluctuated between systolic and a non-zero pressure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-35, 37 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev et al. Shalev et al discloses a method of treating a heart as discussed above. However, Shalev et al remains silent as to placing a conduit in the passage or forming the passage. It is well known in the art of heart treatment to either placing a conduit in the passage (stent) or forming the passage (coronary artery bypass) or both (coronary artery bypass using a graft or anastomosis device) for the purpose of bypassing a constriction in the coronary artery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent or coronary artery bypass to bypass a constriction in the coronary artery.

With regard to claims 35, 37 and 43-44, Shalev et al remains silent as to measuring the mean wedge pressure. Mean wedge pressure is a well-known method of measuring vessel pressure using a balloon for the purpose of determining hemodynamic effect. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize measuring the mean wedge pressure in order to determine hemodynamic effect.

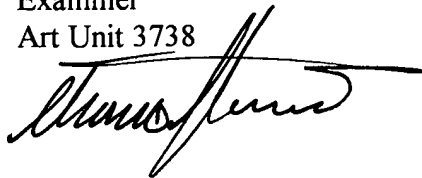
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner
Art Unit 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', with a long horizontal stroke extending to the right.